

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

**REMARKS**

Reconsideration is requested.

The Examiner is requested to acknowledge receipt of a certified copy of the priority document from the International Bureau. The following is a reproduction of Forms PCT/IB/304 and PCT/IB/308, confirming that a certified copy of the priority document was forwarded to the USPTO by WIPO.

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

PATENT COOPERATION TREATY

PCT/EP03/02925

From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE  
COMMUNICATION OF THE INTERNATIONAL  
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
PEAUCELLE, Chantal Cabinet Armengaud Aine 3, Avenue F-75116 Paris FRANCE
ARMENGAUD AINE R.F.C.
23. SEP. 2003

Date of mailing (day/month/year) 12 September 2003 (12.09.03)	Applicant's or agent's file reference CP 60612	
IMPORTANT NOTICE		
International application No. PCT/EP03/02925	International filing date (day/month/year) 06 March 2003 (06.03.03)	Priority date (day/month/year) 06 March 2002 (06.03.02)
Applicant MUTABILIS SA		

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this notice:

AU, AZ, BY, CH, CN, CO, DE, DZ, HU, JP, KG, KP, KR, MD, MK, MZ, RU, TM, US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirements for such a communication at this time:

AE, AG, AL, AM, AP, AT, BA, BB, BG, BR, BZ, CA, CH, CU, CZ, DK, DM, EA, EC, EE, EP, ES, FI, GB, GD, GE, GH, GM, HR, ID, IL, IN, IS, KE, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MG, MN, MW, MX, NI, NO, NZ, OA, OM, PH, PL, PT, RO, SC, SD, SE, SG, SK, SL, TJ, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this notice is a copy of the international application as published by the International Bureau on 12 September 2003 (12.09.03) under No. 03/074553

4. TIME LIMITS for filing a demand for international preliminary examination and for entry into the national phase

The applicable time limit for entering the national phase will, subject to what is said in the following paragraph, be 30 MONTHS from the priority date, not only in respect of any elected Office if a demand for international preliminary examination is filed before the expiration of 19 months from the priority date, but also in respect of any designated Office, in the absence of filing of such demand, where Article 22(1) as modified with effect from 1 April 2002 applies in respect of that designated Office. For further details, see PCT Gazette No. 44/2001 of 1 November 2001, pages 19926, 19932 and 19934, as well as the PCT Newsletter, October and November 2001 and February 2002 issues.

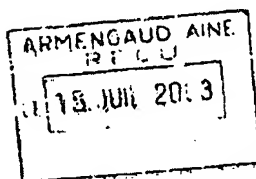
In practice, time limits other than the 30-month time limit will continue to apply, for various periods of time, in respect of certain designated or elected Offices. For regular updates on the applicable time limits (20, 21, 30 or 31 months, or other time limit), Office by Office, refer to the PCT Gazette, the PCT Newsletter and the PCT Applicant's Guide, Volume II, National Chapters, all available from WIPO's Internet site, at <http://www.wipo.int/pct/en/index.html>.

For filing a demand for international preliminary examination, see the PCT Applicant's Guide, Volume I/A, Chapter IX. Only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination (at present, all PCT Contracting States are bound by Chapter II).

It is the applicant's sole responsibility to monitor all these time limits.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Judith Zahra
Facsimile No. (41-22) 740.14.33	Telephone No. (41-22) 338.91.11

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008



# PATENT COOPERATION TREATY

PCT

## NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

From the INTERNATIONAL BUREAU

To:

PEAUCELLE, Chantal  
Cabinet Armengaud Aine  
3, Avenue Bugeaud  
F-75116 Paris  
France

Date of mailing (day/month/year) 02 July 2003 (02.07.03)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference CP 60612	
International application No. PCT/EP03/02925	
International publication date (day/month/year) Not yet published	
Applicant MUTABILIS SA et al	International filing date (day/month/year) 06 March 2003 (06.03.03)
	Priority date (day/month/year) 06 March 2002 (06.03.02)

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
3. An asterisk(\*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
4. The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
06 Marc 2002 (06.03.02)	02290556.6	EP	15 May 2003 (15.05.03)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 338.89.75 Form PCT/IB/304 (July 1998)	Authorized officer M. CHEVALLAY WORLEY (Fax 3388975) Telephone No. (41-22) 338 8859 005726048
---	--

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

The Examiner's comments on page 2 of the Office Action dated April 14, 2008 indicate that the Examiner has considered the priority document. A copy of the same is contained in the PTO PAIR IFW. The Examiner is requested to update the BIB DATA SHEET in the PTO PAIR to confirm that foreign priority has been claimed and the Examiner is requested to confirm in a further Office Action that a certified copy of the priority document has been received.

Claims 1, 3-8, 13, 14 and 17 have been canceled, without prejudice. Claims 2, 9, 10, 11, 12, 15, 16, and 18-29 are pending. Claims 22-29 have been added. Claims 15, 20 and 21 have been withdrawn from consideration. Claims 22-29 are believed to read on the elected subject matter. Rejoinder and allowance of claims 15, 20 and 21, with the remaining pending claims are requested.

The claims have been amended, without prejudice, to define polypeptides which are antigenic fragments of SEQ ID NO:134, as well as compositions containing same or a polypeptide having the sequence set forth in SEQ ID NO:134 and uses of same. No new matter has been added.

Claim 2 have been amended to obviate the objection to same stated on page 3 of the Office Action dated April 14, 2008. Withdrawal of the objection is requested. The objections of claims 9, 10 and 18 are believed to be obviated by the above amendments. Withdrawal of the objections are requested. The objection to claim 11 is at least partially obviated by the above amendment. As for the recitation of "administerable", which is a basis of the objection to claim 11, the Examiner is requested to appreciate that the Patent Office on-line data base indicates that 126 U.S.

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

patents have issued since 1976 which contain the word "administerable" in the claims.

The following is a listing of the most recently-issued 50 of these U.S. Patents:

PAT. NO.

- 7,056,893    Topical treatment for prevention of ocular infections
- 7,008,928    Tetrapeptide derivative TZT-1027 crystal
- 6,887,897    Calcium glutarate supplement and phosphorus binder
- 6,814,983    Compositions and methods for nutrition supplementation
- 6,745,940    Method for the secure handling of monetary or value units using prepaid data carriers
- 6,733,797    Neuroceutical for improving memory and cognitive abilities
- 6,572,854    Use of bacteria endowed with arginine deiminase to induce apoptosis and/or reduce an inflammatory reaction and pharmaceutical or dietetic compositions containing such bacteria
- 6,551,626    Composition containing pyrrolizidine-alkaloid-free petasites
- 6,514,524    Orally administerable immediate-release and prolonged-release galenic form comprising an absorption-promoting agent and use of this absorption-promoting agent
- 6,495,120    Formulation and system for intra-oral delivery of pharmaceutical agents
- 6,472,439    Medicinal plant dry extracts
- 6,426,087    Orally administrable immediate-release and prolonged-release galenic form comprising an absorption-promoting agent and use of this absorption-promoting agent
- 6,417,197    Acylated n-hydroxy methyl thalidomide prodrugs with immunomodulator action
- 6,398,771    Containers for parenteral fluids
- 6,328,998    Composition comprising L-carnitine or an alkanoyl L-carnitine and long-chain alkanols
- 6,251,909    Arylglycinamide derivatives, methods of producing these substances and pharmaceutical compositions containing such compounds
- 6,238,371    Device for acclimatization to therapy by injections
- 6,211,179    Nitrosated and nitrosylated phosphodiesterase inhibitor compounds, compositions and their uses
- 6,200,604    Sublingual buccal effervescent
- 6,180,680    Pharmaceutical compositions comprising alkanoyl L-carnitine in combination with a statine for treating pathologies brought about by an altered lipid metabolism
- 6,162,464    Non-aqueous colonic purgative formulations
- 6,160,020    Alkali metal and alkaline-earth metal salts of acetaminophen

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

- 6,126,969 Immediate release/sustained release compressed tablets
- 6,126,965 Liposomes containing oligonucleotides
- 6,126,958 Intravaginal rings with insertable drug-containing core
- 6,120,787 Sustained release particles
- 6,054,555 Process for the preparation of immobilized and activity-stabilized complexes of LHRH antagonists
- 5,997,903 Oral-administration forms of a medicament containing pantoprazol
- 5,989,578 Associations of active principles containing clopidogrel and an antithrombotic agent
- 5,972,383 Solid orally administerable raloxifene hydrochloride pharmaceutical formulation
- 5,972,372 Intravaginal rings with insertable drug-containing core
- 5,965,153 Dietary supplement for preventing or reducing shedding by animals
- 5,919,478 Incorporating poly-N-vinyl amide in a transdermal system
- 5,881,534 Process for sterilization by radiation and by the use of an oxygen absorber, a container and a medical article sterilized by the process
- 5,879,714 Controlled-release pharmaceutical compositions
- 5,811,120 Solid orally administerable raloxifene hydrochloride pharmaceutical formulation
- RE35,862 Delivery systems for pharmacological agents encapsulated with proteinoids
- 5,719,123 Ciclosporin form for pulmonary administration
- 5,701,937 Fluid distribution system
- 5,599,557 Stable hydrated cephalosporin dry powder for oral suspension formulation
- 5,580,579 Site-specific adhesion within the GI tract using nanoparticles stabilized by high molecular weight, linear poly (ethylene oxide) polymers
- 5,505,959 Pharmaceutical composition in gel form in a dispensing package
- 5,504,105 Pharmaceutical compositions containing ipriflavone, process for the preparation thereof and relative therapeutic use
- 5,468,466 Compositions of iodophenyl sulfonates for X-ray visualization of the gastrointestinal tract
- 5,393,535 Orally administerable calcium supplement for cattle
- 5,384,831 System for providing personalized telephone calling features
- 5,368,839 Insoluble salts of lanthanides for the visual display using nuclear magnetic resonance, of the gastro-intestinal tract
- 5,348,979 Method of promoting nitrogen retention in humans
- 5,348,727 Compositions of iodophenoxy alkylene ethers for visualization of the gastrointestinal tract
- 5,344,638 Compositions of iodobenzoic acid derivatives for visualization of the gastrointestinal tract

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

The above is believed to be sufficient evidence the support the applicants belief that the objected-to terms has been acceptable to the Patent Office in previously-issued claim language and that the applicants use of the term should also be acceptable. Withdrawal of the objection to claim 11 is requested.

The Section 112, first paragraph "enablement", rejection of claims 10-12 and 16 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following and attached publication of Durant et al ("Identification of Candidates for a Subunit Vaccine Against Extraintestinal Pathogenic *Escherichia coli*", Infection and Immunity, Apr. 2007, p 1916-1925).

The applicants submit that the one of ordinary skill in the art will be able to make and use the claimed invention from the teachings of the specification without undue experimentation.

The attached Durant et al describes the use of a peptide C3389 (antigen no. MPV41) with a GenBank accession no. AAN81834 (see Table 2 of the reference) which is demonstrated in the attached to provide protection of mice from lethal challenge with ExPEC strain S26 (see Tables 3 and 4 of the attached). Moreover, Table 5 of the attached, and the accompanying discussion, demonstrates that human sera detected the C3389 antigen of the reference, indicating "that native proteins are expressed during the infectious process and that antigens can induce an antibody response in the host". See page 1922, right column, end of RESULTS, of Durant et al.


The applicants note that the protein sequence of GenBank accession no. AAN81834 is the same, except for the first amino acid, of SEQ ID NO:134 of the

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

present application. The following is a copy of GenBank accession no. AAN81834  
obtained from <http://www.ergo-light.com/ERGO/CGI/> on September 14, 2008:

External Entry for tn|AAN81834

Page 1 of 2



10 genomes   Statistics   **Integrated Genomics**

Data   Query   Help

All Organisms ->   Data   Query

ID   AAN81834   standard; genomic DNA; PRO; 1653 BP.

XX

IV   AAN81834.1

XX

PA   AE016765.1

XX

DE   Escherichia coli CFT073 Hypothetical protein

XX

OS   Escherichia coli CFT073

OC   Bacteria; Proteobacteria; Gammaproteobacteria; Enterobacteriales;

OC   Enterobacteriaceae; Escherichia.

OX   NCBI\_TaxID=159310;

XX

FH   Key   Location/Qualifiers

FH

FT   CDS   AE016765.1:205093..206745

FT   /codon\_start=1

FT   /db\_xref="GOA:Q8FED6"

FT   /db\_xref="InterPro:IPR006664"

FT   /db\_xref="InterPro:IPR006665"

FT   /db\_xref="UniProt/TREMBL:Q8FED6"

FT   /note="Residues 6 to 550 of 550 are 41.51 pct identical to

FT   residues 6 to 562 of 578 from GenPept.129 :

FT   >emb|CAC90294.1| (AJ414148) putative exported protein

FT   [Yersinia pestis]"

FT   /transl\_table=11

FT   /gene="c3359"

FT   /product="Hypothetical protein"

FT   /protein\_id="AAN81834.1"

FT   /translation="MRNTLFQAIIVLWGMVLLVLM3VFISPSGVLRWAGAAIVLAVAA

FT   LLIVRRRQAWTEMTGDAGLSSLPETRYRQPVVLVCGGLSAHLSTSEFVRQVSEGLYLHV

FT   PDEEQLVAQVERLLTLRPAMASQLAVAYTIMPGIHRDVAVLAGRLRRFAHSMATVRRRA

FT   GVNVPWLLWSGLSGSPLPERASSPWFICTGGEVQVATSTETTMPAQWIAQSGVQERSQR

FT   LCYLLKRAESILMQWLNINLVLTALNGPEAKCPPLAMTVGLVPSLPVAVNNLWQLWITARTG

FT   LTPDIADTGTDALPFPDALLRLQFLRQSGFTFLRRACVTMLGVTTVAGIAALCLSATAN

FT   RQLLRQVGDLLHRFYAVPVVEEFITKARHL5VLKDDATMLDGYVREGEPLRLGLGLYPGE

FT   RIRQFVLRAIRDWRPPEQKMEVTASLQVQTVRLDSMSLFDVGQARLKDGS TKVLVDALV

FT   NIRAKPGWLILVAGYTDATGDEKSNQQLSLRFAEAVRNKMLQTS DIPATCFVAVOGLGES

FT   QPAATNDTPQGRAVNRREI5LVPRSDACQDVK"

XX

SQ   Sequence 1653 BP; 307 A; 477 C; 540 G; 329 T; 0 other; 2639092998 CRC32;

gtgaggaaca cgctgaaaca ggccatcgty ctgtggggaa tgggtgttact gctgggtgctg 60

tggtcagtggt ttatcagtcgc gtctggcgty ctgagatggg cgggtgcggc ggctatcggt 120

ctggcggttg cgcgctgtgt gatttatcgg cgcaggcagg cgtggacgga gatgaccggc 180

gatgccgggt tytcacgcgt gccgccggaa acctaccgac agccggtagt gctgggtctgt 240

ggcggtctgt cggcgccact gtccactgac agcccggtcc gccaggttcc agaagggctg 300

tatctgcatg ttccctgatga agaaccgctt gtggcgccagg tggagcgatt gctgaccctt 360

cgcgccggct gggaatcgca gcttgccgtg gcgtatacca tcatgcccgg catacaccgg 420

gatgtggcgg ttctggccgg acggctgcga cggttcgccc acagtatgc gacgggtgct 480

cgtcgggcag gcgtaaacgt cccctggctt ctctggagcg ggcgtcccg ctcgccgttg 540

<http://www.ergo-light.com/ERGO/CGI/prot.cgi?prot=tn%7CAAN81834&user=>

9/14/2008



ESCAICH, S.  
 Appl. No. 10/506,666  
 Atty. Ref.: 1721-81  
 Amendment  
 Monday, September 15, 2008

External Entry for tn|AAN81834

Page 2 of 2

```

ccggaagag cgagttcacc gtggtttatc tgtaccggcg gcgaagtcca ggtagcaaca 600
tccacagaga ccaccatgcc cgcgcagtggt attgcacaat ccggcgtaca ggagcgagcgt 660
cagcgactct gttacctgct gaaagctgaa agcctgatgc agtggctgaa tcttaatgtg 720
ctgacggcac tgaacggccc ggaggcgaaa tgtccaccac tggcgatgac cgtggggctg 780
gtccctcgt tgcttgcggt ggataacaac ctgtggcagt tgtggatcac cgcagaacc 840
ggcctgacgc cggatatcgc ggacaccggc acagacgatg cgtggcatt ccggatgcc 900
ctgttacggc agttgccgcg tcagtcgggc ttaccctgc tgccagcagc ctgcgtgacc 960
atgctgggcy tcaccaccgt ggcgggtatc gccgcgctgt gcctgtcagc caccgcaaat 1020
cgccagttat tacggcaggt cggtgacgat ctgcaccggc ttatgcccgt ccgggtggag 1080
gaatttatca ccaaagcccgc tcacctgtcg gtgctgaaag acgatgagc catgctcgat 1140
gggtattacc gggaaggaga acccttgcgc ctgggtcttg ggttatcccc cggcgaacgc 1200
atccgccagc cgggtattacg cgccattcgc gactggcgtc ccctgaaca aaaaatggag 1260
gtgacggctt cgcttcaggt tcagaccgtg cgtcttgaca gtatgtcgt gtttgacgtc 1320
ggacaggccc gcctgaaaga cggctcgaca aaagtgcctg tggacgcact ggtgaacatc 1380
cgggcaaac cgggctggct gatcctcgtg gccggatata ccgatgccac cggcgatgaa 1440
aaaagcaatc agcagttatc gctgcggcgt gccgaagcgg tgcgcaactg gatgctgcag 1500
accagcgaca tcccgccac ctgttttgcc gtacagggac tgggcgagag ccagcctgcg 1560
gcgaccaacg acacgccaca gggccgggca gtcaaccggc gtgtcgaaat cagtcttgtt 1620
ccgcgttctg acgcctgtca ggacgtgaaa taa 1653

```

//

Contact

IG genome releases

ERGO™

ERGO plants

ERGO publications

The following is a result of BLAST comparison of SEQ ID NO:134 of the present application with the above listing of GenBank accession no. AAN81834:



## Blast 2 Sequences results

PubMed

Entrez

BLAST

OMIM

Taxonomy

Structure

### BLAST 2 SEQUENCES RESULTS VERSION BLASTP 2.2.18 [Mar-02-2008]

Matrix BLOSUM62 gap open: 11 gap extension: 1

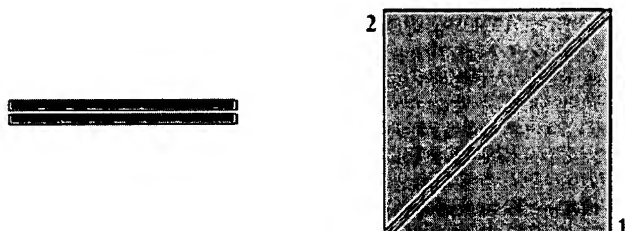
x\_dropoff: 0 expect: 10.000 wordsize: 3 Filter ☒ View option Standard

Masking character option X for protein, n for nucleotide Masking color option Black

☐ Show CDS translation

Sequence 1: unnamed protein product  
Length = 550 (1 .. 550)

Sequence 2: unnamed protein product  
Length = 550 (1 .. 550)



NOTE: Bitscore and expect value are calculated based on the size of the nr database.



Score = 952 bits (2460), Expect = 0.0  
Identities = 549/550 (99%), Positives = 550/550 (100%), Gaps = 0/550 (0%)

Query	1	VRNTLKQAIIVLWGMVLLLVLSVFI	SPSGVLRWAGAAAIVLAVAALLIYRRQ	AWTEMTG	60
Sbjct	1	MRNTLKQAIIVLWGMVLLLVLSVFI	SPSGVLRWAGAAAIVLAVAALLIYRRQ	AWTEMTG	60
Query	61	DAGLSSLPFET	YRQPVVLVCGGLSAHLSTDSPVRQV	SEGLYLVHPDEEQLVAQVERLLTL	120
Sbjct	61	DAGLSSLPFET	YRQPVVLVCGGLSAHLSTDSPVRQV	SEGLYLVHPDEEQLVAQVERLLTL	120
Query	121	RFAWASQLAVAYT	IMPGIHRDVAVL	AGRLRRFAHSMATVRRPAGVNVFWLLWSGLSGSPL	180
Sbjct	121	RFAWASQLAVAYT	IMPGIHRDVAVL	AGRLRRFAHSMATVRRPAGVNVFWLLWSGLSGSPL	180
Query	181	PERASSPWFICTG	GEVQVATSTETTMPAQWIAQSGVQERSQRLCYLLKAESLMQWLN	LN	240
Sbjct	181	PERASSPWFICTG	GEVQVATSTETTMPAQWIAQSGVQERSQRLCYLLKAESLMQWLN	LN	240

ESCAICH, S.  
 Appl. No. 10/506,666  
 Atty. Ref.: 1721-81  
 Amendment  
 Monday, September 15, 2008

Blast Result

Page 2 of 2

Query	241	LTALNGPEAKCPFLAMTVGLVPSLPAVDNNLWQLWITARTGLTPDIADTGTDDALPFFDA	300
		LTALNGPEAKCPFLAMTVGLVPSLPAVDNNLWQLWITARTGLTPDIADTGTDDALPFFDA	
Sbjct	241	LTALNGPEAKCPFLAMTVGLVPSLPAVDNNLWQLWITARTGLTPDIADTGTDDALPFFDA	300
Query	301	LLRQLPRQSGFTPLRRACVTMLGVTTVAGIAALCLSATANRQLLRQVGDDLHREFYAVPVE	360
		LLRQLPRQSGFTPLRRACVTMLGVTTVAGIAALCLSATANRQLLRQVGDDLHREFYAVPVE	
Sbjct	301	LLRQLPRQSGFTPLRRACVTMLGVTTVAGIAALCLSATANRQLLRQVGDDLHREFYAVPVE	360
Query	361	EFITKARHLSVLKDDATMLDGYREGEPLRLGLGLYPGERIQPVLRRAIRDWRPPEQKME	420
		EFITKARHLSVLKDDATMLDGYREGEPLRLGLGLYPGERIQPVLRRAIRDWRPPEQKME	
Sbjct	361	EFITKARHLSVLKDDATMLDGYREGEPLRLGLGLYPGERIQPVLRRAIRDWRPPEQKME	420
Query	421	VTASLQVQTVRLDSMSLFDVGQARLKDGSTKVLVDALVNIRAKPGWLILVAGYTDATGDE	480
		VTASLQVQTVRLDSMSLFDVGQARLKDGSTKVLVDALVNIRAKPGWLILVAGYTDATGDE	
Sbjct	421	VTASLQVQTVRLDSMSLFDVGQARLKDGSTKVLVDALVNIRAKPGWLILVAGYTDATGDE	480
Query	481	KSNQQLSLRRAEAVRNWMLQTS DIPATCF AVQGLGESQPAATNDTPQGRAVNR RVEISLV	540
		KSNQQLSLRRAEAVRNWMLQTS DIPATCF AVQGLGESQPAATNDTPQGRAVNR RVEISLV	
Sbjct	481	KSNQQLSLRRAEAVRNWMLQTS DIPATCF AVQGLGESQPAATNDTPQGRAVNR RVEISLV	540
Query	541	PRSDACQDVK	550
		PRSDACQDVK	
Sbjct	541	PRSDACQDVK	550

CPU time: 0.05 user secs. 0.03 sys. secs 0.08 total secs.

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

For completeness, the applicants note that antigen FyuA of the attached Durant et al is SEQ ID NO:2 of the present application, antigen IroN of the attached Durant et al is SEQ ID NO:8 of the present application; antigen C0393 of the attached Durant et al is SEQ ID NO:26 of the present application; and antigen C4424 of the attached Durant et al is SEQ ID NO:34 of the present application.

Table I of the Remarks of the Amendment filed July 17, 2007 is believed to include information published in Table 5 of the attached Durant et al. Table II of the Remarks of the Amendment filed July 17, 2007 is believed to include information similar to the information published in Table 3 of the attached Durant et al.

The attached is submitted as objective evidence that the polypeptide having a sequence set forth in SEQ ID NO:134 is capable of providing a protective immune response.

The claims are submitted to be supported by an enabling disclosure as one of ordinary skill in the art would have been able to make and use the claimed invention from the teaching of the specification and the generally advanced level of skill in the art.

Withdrawal of the Section 112, first paragraph "enablement", rejection is requested.

The Section 102 rejection of claims 1, 2, 9-12, 16, 18 and 19 over Bingen (WO 01/066572), is traversed. Reconsideration and withdrawal of the rejection are requested as the cited art fails to teach each and every aspect of the claimed invention.

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

The applicants believe the teaching of SEQ ID NO:784 of the cited art fails to literally or inherently provide compositions or methods of the presently claimed invention.

The claimed compositions require a pharmaceutically acceptable carrier which the applicants believe to not be specifically described in conjunction with SEQ ID NO:784 of the cited art and/or require antigenic fragments of the sequence set forth in SEQ ID NO:134 which are not believed to be described in the cited art.

Moreover, as noted above, the attached is submitted as objective evidence that the polypeptide having a sequence set forth in SEQ ID NO:134 is capable of providing a protective immune response.

The passages identified in the reference by the Examiner, i.e., page 3, lines 25-34; page 13, line 24 to page 14, line 4 and page 130, lines 5-20 (see pages 11-12 of the Office Action dated April 14, 2008), describe the following:

... of E. coli, and more particularly a development of E. coli in a human or animal compartment which is extra-intestinal (systemic and non-diarrhoea<sup>1</sup> infections, such as septicaemia, pyelonephritis, or meningitis in the newborn). The present invention in fact provides, in addition to the diagnostic and therapeutic means directed against E. coli in general, specific diagnostic and therapeutic means which have the advantage of distinguishing between E. coli capable of infecting the ...

A subject of the present application is also any composition, in particular any pharmaceutical composition, comprising at least one compound chosen from the group consisting of the novel polynucleotides which are of novel nature B2/D+ A-, the polypeptides corresponding to at least one novel polynucleotide which is of novel nature B2/D+ A-, and the vectors and cells according to the invention, mentioned above. Such compositions are in particular useful for treating

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

and/or for alleviating and/or for preventing E. coli infections, and in particular of infection by extra-intestinal E. coli (systemic and non-diarrhoea infections). When said compound is immunogenic or is made immunogenic, these compositions can correspond to vaccines.

... after 24 hours of acclimatisation in animal houses were infected when 5 days old. The injected inoculum was prepared from dilutions in physiological serum in a nutritive culture medium of 2 h. The animals were infected by intra-peritoneal route after anesthesia with ether, then put back to their mother after randomization by brood of ten.

The numeration of the bacteraemia at 18h was obtained by taking of 5 µl of blood after incision of the tail.

'Bacteraemia at H18 (%) of 4 days old rats after intra peritoneal injection of various strains of E. coli.

GROUP	STRAIN	INOCULUM		
		100 bacteria	10000 bacteria	1000000 bacteria
B2	C5	100%	ND*	ND*
B2	CFT073	0%	0%	all dead 100%
A	S82	0%	0%	66%
D	S16	25%	64%	ND*

\* : ND not done

The cited passages fail to specifically or inherently teach the claimed compositions and/or methods.

The claimed invention is submitted to be patentable over the cited art and withdrawal of the Section 102 rejection is requested.

To the extent not obviated by the above amendments, the Section 101 rejection of claims 9, 18 and 19 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the above and the following comments.

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

The isolated products of claim 9 are not believed to have been demonstrated as existing in nature. Moreover, the claims are not believed to read on "strains" as suggested by the Examiner on page 12 of the Office Action dated April 14, 2008. The compositions of claims 18 and 19 are also not believed to exist in nature. Withdrawal of the Section 101 rejection is requested.

The Section 112, second paragraph rejection of claim 1 is moot in view of the above.

The Section 112, second paragraph, rejection of claim 2 is obviated by the above amendments. Withdrawal of the Section 112, second paragraph, rejection of claim 2 is requested.

Claim 11 is not believed to be "vague". While claim 11 is not included in the statement of rejected claims on page 12 of the Office Action dated April 14, 2008, the Examiner's comment on page 13 regarding same may suggest the Examiner intended to include claim 11 in the rejection under Section 112, second paragraph. The applicants believe one of ordinary skill will appreciate that compositions may be formulated differently depending on the treatment indication. Treatment formulations for neonates will be appreciated to be different than those for adults or children, for example. Moreover, treatment of urinary system infection will suggest distinct formulation and/or administration modalities. Claim 11 is submitted to be definite.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned in the event anything further is required in this regard.

ESCAICH, S.  
Appl. No. 10/506,666  
Atty. Ref.: 1721-81  
Amendment  
Monday, September 15, 2008

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By:                     /B. J. Sadoff/                      
                    B. J. Sadoff  
                    Reg. No. 36,663

BJS:  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100